IN THE UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DAWN TUCKER, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:20-cv-01543-RLW
	)	
ETHICON, INC. and JOHNSON & JOHNSON,	)	
	)	
Defendants.	)	

DEFENDANTS' MOTION *IN LIMINE* NO. 2
TO EXCLUDE CERTAIN IRRELEVANT AND UNFAIRLY PREJUDICIAL COMPANY DOCUMENTS AND EMAILS

Defendants Ethicon, Inc. and Johnson & Johnson move *in limine* for an order excluding the following company documents produced during general discovery in this litigation.

ARGUMENT

I. Dr. Meng Chen's December 2008 and January 2009 email strings discussing the IFUs for the TVT family of products should be excluded.

In a December 2008 email discussion with Sergio Gadaleta and Mark Yale and a January 2009 email discussion with Bryan Lisa, Ethicon medical director Dr. Meng Chen discussed potential updates to the IFUs for the TVT family of products in light of a Public Health Advisory from the FDA. *See* Ex. 1, 2008 email chain; Ex. 2, 2009 email chain. These emails should be excluded for several reasons.

First, Plaintiffs cannot identify how this evidence relates to any element of their claims against Ethicon. These emails are simply one individual's query as to whether the FDA's advisory – which was an official and highly publicized notice to doctors and the general public – also needed to be reflected in product IFUs. Because a manufacturer does not need to warn of risks that are

already generally known, the FDA advisory did not impose any additional duties on Ethicon. *See Grady v. Am. Optical Corp.*, 702 S.W.2d 911, 915 (Mo. App. 1985) ("[M]anufacturers and distributors are not under a duty to provide warnings about dangers which are open and obvious, or which are commonly known."). Plaintiffs' introduction of this testimony would only confuse and prejudice the jurors.

If the Court were to permit Plaintiffs to open the door to what Dr. Chen was evaluating and why, fairness would require that Defendants be allowed to present evidence of the entire chain of events that followed Dr. Chen's inquiry, including Ethicon's responses to the FDA publications. The adequacy of the design and warnings for TVT-Secur and Prolift cannot be determined by the questions raised by one employee without understanding what prompted the question—and what prompted Ethicon to continue to study its products. A proper explanation of Dr. Chen's statements would require reference to the FDA' regulation of pelvic mesh products, a subject the parties have agreed will not be admissible at trial. To prevent the unnecessary expenditure of resources needed to explain this collateral issue, this Court should exclude these email chains.

II. The PA Consulting Group Report, *Investigatng Mesh Erosion in Pelvic Floor Repair* should be excluded.

The June 2011 report prepared by PA Consulting Group for the investigation of a new pelvic organ prolapse product, titled "Investigating Mesh Erosion in Pelvic Floor Repair" (the "Report") is inadmissible hearsay, is irrelevant, and its admission would unfairly prejudice Defendants, unnecessarily delay the trial, and confuse and mislead the jury. *See* Ex. 3.

A. The Report is inadmissible hearsay.

This Report was not authored by Ethicon or Johnson & Johnson and therefore is not a statement by a party under Federal Rule of Evidence 801(d)(2). Further, none of the authors of the report will be called at trial to lay a foundation that the business records exception might apply.

B. This evidence will confuse the jury and result in trial delay.

The references multiple products that are not at issue here (including products that Ethicon does not manufacture), various studies and literature, multiple surgical methods for mesh implantation, variables that may affect erosion (including patient characteristics and co-morbidities), and the skills of the surgeon implanting the mesh as factors affecting mesh erosion. *See* Ex. 3, Report at 7, 9, 11, 14-15, 32, 39. This will confuse the jury and distract them from the relevant issues. In addition, the presentation of this evidence necessarily will prolong the trial on peripheral issues that Defendants would need to rebut, even though they have nothing to do with the product at issue. As a result, the Court should exclude the Report under Rule 403 as well.

III. The 1997 License and Supply Agreement between Medscand and Johnson & Johnson International and evidence of related payments should be excluded.

Evidence concerning "milestone payments" made under a 1997 License and Supply Agreement between Medscand (the original developer of TVT) and Johnson & Johnson International should be excluded. Plaintiffs may offer this to suggest that Ethicon somehow manipulated the development process for TVT – a predicate device for TVT-Secur – by paying the developer to generate favorable data. Any such accusation is inadmissible no matter who makes it and is an incorrect interpretation of the contract in question.

Under this contract, Johnson & Johnson International bought the rights to a product in development from the product's inventor, Dr. Ulmsten. The portion of the contract that Plaintiffs may wish to paint as sinister called for "milestone payments" totaling $400,000, payable to Ulmsten at specified stages in the development of the product. In other words, the contract merely provided that both the seller and the buyer would share the risk if at some point in the development process it would become apparent that the product would not be commercially viable. *See* Ex. 4, March 1997 Medscand Agreement at 7-8. These agreements make it possible for an inventor with

an idea to obtain development support and, in the event of success, obtain full value for his or her idea. At the same time, the provisions make it possible for an investor to avoid paying full price and ending up with only "Blue Sky."

Pursuant to Rules 401, 402, and 403, the Court should bar any testimony, argument, or suggestion that Ulmsten was bribed to provide a favorable result. Plaintiffs may argue that this evidence is relevant to show alleged bias in the development of TVT, but that is entirely speculative and ultimately irrelevant to Plaintiffs' claims involving TVT-Secur. Not only is there no evidence that Ulmsten actually did anything unethical, but extensive subsequent testing has shown just the opposite. The ultimate test in science is the ability to replicate results, and Ulmsten's results have been repeated by others over the past decades. Since 1998, there have been at least 100 controlled studies of TVT at other centers that have verified Ulmsten's results. *See* Ex. 5, Sept. 25, 2013 Dep. of Axel Arnaud at 889:11-25. In the face of the overwhelming evidence that Ulmsten did not bias his testing or act unethically, speculation about bias in an original study of a product not at issue in this case that was conducted more than 20 years ago is irrelevant.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court issue an Order excluding the above-referenced documents.

STATEMENT REGARDING CONFERENCE

In accordance with this Court's Case Management Order (Doc. 79), counsel for Defendants certifies that they have met and conferred with counsel for Plaintiffs by telephone in a good faith attempt to resolve the dispute presented by this motion, and counsel for Plaintiffs would not agree to the relief requested herein.

Dated: October 12, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 12th day of October, 2021, a true and correct copy of the foregoing instrument was electronically filed with the Clerk of Court and served to all counsel of record via the Court's CM/ECF system.

/s/ Cicely I. Lubben
Attorney for Defendants Ethicon, Inc. and Johnson & Johnson